IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	: Examiner: Christopher Bull
Michael John Blackman	: Group Art Unit: 1655
Serial No.: 10/501,131	:
Filed: July 9, 2004	:
Entitled: "Fluorogenic	:
Protease Substrates"	:

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Certificate of Mailing Under 37 C.F.R. §1.8(a):

I hereby certify that this correspondence is being deposited on December 23, 2005 with the United States Postal Service as first-class mail in an envelope properly addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Caren Burgoon

Caren Burgoon

Petition for Extension of Time Under 37 C.F.R. §1.136(a):

The undersigned hereby petitions for an extension of time of one (1) month beyond the time period set in the last Office Action. A check in the amount of $120.00 to cover this fee is enclosed. Please charge any deficiency or credit any overpayment to Deposit Account No. 04-1406.

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TRAVERSAL AND REQUEST FOR RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

Dear Sir:

Applicant, through his undersigned attorneys, hereby traverses and requests reconsideration of the requirement for restriction set forth in the Official Action dated October 31, 2005 in the above-identified

patent application.

At the outset, it is noted that an initial shortened statutory response period of one (1) month was set in the October 31, 2005 Official Action. Accordingly, the initial due date for response was November 30, 2005. A Petition for a one (1) month extension of the initial response period is presented concurrently with this Traversal And Request For Reconsideration Of Requirement For Restriction which is being filed before the expiration of the one (1) month extension period.

The restriction requirement in this case is plainly improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in 1893.03(d) of the M.P.E.P.:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371...
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention

> that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.
>
> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art....

In the present case, all of the claims of Groups I, III and IV recite the same special technical feature, i.e. a fluorogenic protease substrate having the characteristics specified in claim 1. Neither the "standard protease composition" called for in claim 29, nor the "solid substrate" called for in claim 31 constitute "technical features that define the contribution which each claimed invention, considered as a whole, make over the prior art", as stated in the above-quote from M.P.E.P. §1893.03(d). Therefore, these claim elements should not be taken into account in determining unity of invention.

Furthermore, the PCT unity of invention criteria which the PTO is required to apply to this case

includes PCT Administrative Instructions, Annex B, Part 1, which, in part, provides:

> (c) Independent and Dependent Claims. Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims, By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed-for example, product, process, use or apparatus or means, etc.).

It is clear that the claims of groups III and IV are in the same category as claim 1 (product) and contain all the features of claim 1. Although expressed in the form of independent claims, they are nevertheless dependent within the meaning of the above-quoted instruction, and so should not be subject to an objection for lack of unity. Indeed, this is illustrated by the fact that claims 29 and 31 (of groups III and IV, respectively) could instead be expressed in the following terms:

> 29. A fluorogenic protease substrate according to claim 1, which is a component of a kit for use

in a method of assaying protease activity, the kit also comprising a standard protease composition for calibration of the assay.

31. A fluorogenic protease substrate according to claim 1, which is immobilized on a solid support.

In terms of patentability at least, these claims are equivalent to pending claims 29 and 31 and would be formally dependent.

Thus, the Examiner is impermissibly requiring restriction between an independent claim and claims that, in the context of unity of invention, are dependent from it. If claim 1 is found to be novel and inventive over the prior art, then (like formally dependent claims) claims 29 and 31 will also be novel and inventive by virtue of their inclusion of the novel and inventive fluorogenic protease substrate. Therefore, viewed in this light also, the special technical feature of claims 29 and 31, like that of claim 1, is the protease substrate.

Moreover, given the substantial overlap in subject matter claimed in claims 1, 29 and 31, as discussed above, it is clear that the field of search with respect to the claims of Group I would of necessity include the same areas in which the claims of Groups III and IV are classified. Thus, the concurrent examination of all of these allegedly distinct inventions in the

present application would not materially affect the Examiner's workload.

Inasmuch as the March 19, 2003 Official Action fails to comply with established United States Patent and Trademark Office unity of invention practice, it is respectfully submitted that this requirement should be reconsidered and withdrawn.

In order to be fully responsive to the above-mentioned requirement, applicants hereby elect the subject matter of Group I, i.e. claims 1-12, 19-21 and 32-40 for examination in this application.

It is noted that claim 33, which was presented as a new claim in Applicants' Preliminary Amendment filed July 9, 2004, is omitted from the present restriction requirement. This omission is presumed to be an oversight. As claim 33 is dependent from claim 27, it has been treated, for purposes of this traversal, as within Group I, which includes claim 27.

Applicants' election in response to the present restriction requirement is without prejudice to their right to file one or more continuing applications, as provided in 35 U.S.C. §121, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,

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